CLAIMS:

1 A pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and a steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, preferably the formulation being in a form suitable for nasal or ocular administration.

2 A pharmaceutical formulation according to claim 1, wherein said azelastine is present as azelastine hydrochloride.

3 A formulation according to claim 1 or 2, wherein the steroid is beclomethasone or a pharmaceutically acceptable ester thereof, mometasone or a pharmaceutically acceptable ester thereof, fluticasone or a pharmaceutically acceptable ester thereof, budesonide or cyclosenide, in any chiral form or mixture.

4 A formulation according to claim 3, wherein the steroid is beclomethasone propionate, mometasone furoate, mometasone furoate monohydrate, fluticasone propionate or fluticasone valerate.

5 A formulation according to any of claims 1 to 4, which contains the steroid in an amount from about 50 micrograms/ml to about 5 mg/ml of the formulation.

6 A formulation according to any of claims 1 to 5, wherein the formulation has a particle size of less than about 10 μm, preferably less than 5 μm.

7 A formulation according to any of claims 1 to 6, which is a suspension containing 0.0005 to 2% (weight/weight of the formulation) of azelastine or a pharmaceutically acceptable salt of azelastine, and from 0.5 to 1.5% (weight/weight of the formulation) of said steroid.

8 A formulation according to claim 7, which contains from 0.001 to 1% (weight/weight of the formulation) azelastine, or salt thereof, and from 0.5% to 1.5% (weight/weight of the

formulation) steroid.

9 A formulation according to any of claims 1 to 8, which also contains a surfactant.

10 A formulation according to claim 9, wherein the surfactant comprises a polysorbate or poloxamer surfactant.

11 A formulation according to claim 9 or 10, which contains from about 50 micrograms to about 1 milligram of surfactant per ml of the formulation.

12 A formulation according to any of claims 1 to 11, which also contains an isotonic agent.

13 A formulation according to claim 12, wherein the isotonic agent comprises sodium chloride, saccharose, glucose, glycerine, sorbitol or 1,2-propylene glycol.

14 A formulation according to any of claims 1 to 13, which also contains at least one of a buffer, a preservative and a suspending or thickening agent.

15 A formulation according to claim 14, wherein said preservative is selected from edetic acid and its alkali salts, lower alkyl p-hydroxybenzoates, chlorhexidine, phenyl mercury borate, or benzoic acid or a salt, a quaternary ammonium compound, or sorbic acid or a salt thereof.

16 A formulation according to claim 14 or 15, wherein the suspending agent or thickening agent is selected from cellulose derivatives, gelatin, polyvinylpyrrolidone, tragacanth, ethoxose (water soluble binding and thickening agents on the basis of ethyl cellulose), alginic acid, polyvinyl alcohol, polyacrylic acid, or pectin.

17 A formulation according to any of claims 14, 15 or 16, wherein the buffer comprises a citric acid-citrate buffer.

18 A formulation according to any of claims 14, 15, 16 or 17, wherein the buffer maintains the pH of the aqueous phase at from 3 to 7, preferably 4.5 to about 6.5.

19 A formulation according to any of claims 1 to 18, which is an aqueous suspension or solution.

20 A formulation according to claim 19, which is in the form of an aerosol, an ointment, eye drops, nasal drops, a nasal spray or an inhalation solution.

21 A formulation according to claim 20, which is in the form of nasal drops or nasal spray.

22 A formulation according to claim 20, which is in the form of an aerosol.

23 A pressure packing having a dosage or metering valve, which contains a formulation according to claim 22.

24 A MDI which includes a pressure packing according to claim 23.

25 A formulation according to any of claims 1 to 19, which is in the form of an insufflation powder.

26 A pharmaceutical product comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided in an aerosol formulation preferably together with a propellant typically suitable for MDI delivery, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided in an aerosol formulation preferably together with a propellant typically suitable for MDI delivery, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated.

27 An aerosol formulation preferably suitable for MDI delivery comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, together with a propellant.

28 A pharmaceutical product comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided as an insufflation powder, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided as an insufflation powder, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated.

29 An insufflation powder formulation comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, together with a pharmaceutically acceptable carrier or excipient therefor.

30 A pharmaceutical product comprising (i) azelastine, or a pharmaceutically acceptable salt thereof, and (ii) at least one steroid selected from the group consisting of beclomethasone, fluticasone, mometasone and pharmaceutically acceptable esters thereof, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated.

31 A pharmaceutical formulation comprising (i) azelastine, or a pharmaceutically acceptable salt thereof, and (ii) at least one steroid selected from the group consisting of beclomethasone, fluticasone, mometasone and pharmaceutically acceptable esters thereof, together with a pharmaceutically acceptable carrier or excipient therefor.

32 A nasal spray comprising azelastine, or a pharmaceutically acceptable salt thereof, together with mometasone either as mometasone free base or as mometasone furoate, and a pharmaceutically acceptable carrier or excipient therefor.

33 A pharmaceutical product comprising azelastine hydrochloride and beclomethasone dipropionate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated.

34 A pharmaceutical formulation comprising azelastine hydrochloride and beclomethasone dipropionate, together with a pharmaceutically acceptable carrier or excipient therefor.

35 A pharmaceutical product comprising azelastine hydrochloride and fluticasone propionate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated.

36 A pharmaceutical formulation comprising azelastine hydrochloride and fluticasone propionate, together with a pharmaceutically acceptable carrier or excipient therefor.

37 A pharmaceutical product comprising azelastine hydrochloride and fluticasone valerate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated.

38 A pharmaceutical formulation comprising azelastine hydrochloride and fluticasone valerate, together with a pharmaceutically acceptable carrier or excipient therefor.

39 A pharmaceutical product comprising azelastine hydrochloride and mometasone furoate, as a combined preparation for simultaneous, separate or sequential use in the

treatment of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated.

40 A pharmaceutical formulation comprising azelastine hydrochloride and mometasone furoate, together with a pharmaceutically acceptable carrier or excipient therefor.

41 A pharmaceutical product comprising azelastine hydrochloride and mometasone furoate monohydrate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated.

42 A pharmaceutical formulation comprising azelastine hydrochloride and mometasone furoate monohydrate, together with a pharmaceutically acceptable carrier or excipient therefor.

43 A pharmaceutical formulation substantially as herein described in any of the Examples.

44 A process of preparing a pharmaceutical product according to any of claims 26, 28, 30, 33, 35, 37, 39 or 41, which process comprises providing (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated.

45 A process of preparing a pharmaceutical formulation according to any of claims 1 to 22, 27, 29, 31, 32, 34, 36, 38, 40, 42 or 43, which process comprises admixing a pharmaceutically acceptable carrier or excipient with azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof.

46 A method for the prophylaxis or treatment in a mammal, such as a human, of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated, which method comprises administration of a therapeutically effective amount of a pharmaceutical product according to any of claims 26, 28, 30, 33, 35, 37, 39 or 41, as a combined preparation for simultaneous, separate or sequential use in the treatment of such conditions.

47 A method for the prophylaxis or treatment in a mammal, such as a human, of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated, which method comprises administration of a therapeutically effective amount of a pharmaceutical formulation according to any of claims 1 to 22, 27, 29, 31, 32, 34, 36, 38, 40, 42 or 43.

48 For use in the manufacture of a medicament for the prophylaxis or treatment in a mammal, such as a human, of conditions for which administration of one or more anti-histamine and / or one or more steroid is indicated, a pharmaceutical product according to any of claims 26, 28, 30, 33, 35, 37, 39 or 41, as a combined preparation for simultaneous, separate or sequential use in the treatment of such conditions.

49 A method of treating irritation or disorders of the nose or eye which comprises applying either directly to nasal tissues or to the conjunctival sac of the eyes, as appropriate, a pharmaceutical product according to any of claims 26, 28, 30, 33, 35, 37, 39 or 41, or a pharmaceutical formulation according to any of claims 1 to 22, 27, 29, 31, 32, 34, 36, 38, 40, 42 or 43.

50 A method of treating airway disorders, comprising administering by nebulization to surfaces of the airway a treatment-effective amount of a product or formulation as defined in the preceding claims.